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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/790,669

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Mitta Suresh

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7590

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MEYERTONS, HOOD, KIVLIN, KOWERT & GOETZEL, P.C.
700 LAVACA, SUITE 800
AUSTIN, TX 78701

EXAMINER

FOSTER, MARLEE CHRISTINE

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 11/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/790,669

Applicant(s)

SURESH ET AL.

Examiner

Marlee C. Foster

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28,53,75,97 and 116 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28,53,75,97 and 116 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/21/04, 7/26/04, 4/21/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-28, 53, 75, 97, and 116 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-43 of copending Application No. 10/235295. Although the conflicting claims are not identical, they are not patentably distinct from each other because the apparatus can inherently perform the method steps of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Specification

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See page 32, line 31 and page 45, line 26 of

the specification. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-8, 10, 12-23, and 25 are rejected under 35 U.S.C. 102(a) as being anticipated by Whayne et al. (US Patent 6,887,192). Whayne et al. disclose an apparatus for reinforcing the endocardial surface of ventricle, with reinforcing elements giving the apparatus a first and second predetermined shape. The first shape is configured to be inserted into a catheter, which is moved through the vasculature to the heart (col. 16, lines 2-8). The second predetermined shape is the expanded state in which the structure supports the endocardial surface of the ventricle (as shown in figures 2 and 5). After insertion into the heart, the apparatus is configured to change from a first shape to a second shape (col. 16, lines 17-22). The structural configuration of the apparatus and reinforcing elements are configured to inhibit expansion over a cardiac cycle of a left or right ventricle, while maintaining the heart in the normal contraction and expansion states (col. 4, lines 26-33).

Regarding claims 4, 6, and 12, each reinforcing element is configured to releasably attach to the endocardial surface of the ventricle with anchors, shown in

figure 14B. In its expanded state, the apparatus approximates the size and shape of the portion of the left ventricle (see figure 2).

Regarding claim 5, the second shape of the apparatus of Whayne, or expanded state, is larger than the diameter of the first predetermined shape, or collapsed state, of the apparatus.

Regarding claims 7 and 8, Whayne et al. disclose an adjustment mechanism that is configured to change the dimensions of the reinforcing element. This inherently changes the dimensions of the ventricle, since the reinforcing element and the endocardial surface are coupled by the anchors. See col. 12, lines 2-7 and lines 47-51.

Regarding claims 13 and 14, the apparatus disclosed by Whayne et al. is manufactured from nitinol, a shape memory alloy (col. 5, lines 16-19).

Regarding claims 16, 17, 18, and 19, the reinforcing elements of Whayne et al. comprise a plurality of conduits (shown as 86, 88, and 26) and an elongated member 52 positionable in the conduits that is configured to extend beyond the distal end of the conduits and engage the portion of the endocardial surface when it is activated. As shown in figure 11, the conduits vary in length to approximate the dimensions of the left ventricle. Regarding claims 20 and 21, the apparatus also comprises a number of support elements 30 that couple the conduits together, preventing the overexpansion of the endocardial surface during the cardiac cycle. The conduits are shown in figures 3-8 to radiate outwards from a center region. Regarding claim 23, the center region shown in figures 7 and 8 couples the conduits.

Regarding claim 10, Whayne et al. disclose an activation mechanism 54 for attaching the reinforcing element to the endocardial surface.

Regarding claim 25, the center of the device has an opening that is configured to potentially allow a guidewire to pass through the center (see figure 7), acting to position the apparatus in the ventricle.

3. Claim 28 is rejected under 35 U.S.C. 102(a) as being anticipated by Whayne et al. (US Patent 6,887,192). Whayne et al. disclose an apparatus comprising a reinforcing element that attaches to a portion of the endocardial surface, where the apparatus inhibits the expansion of the endocardial surface over a cardiac cycle of the heart (col. 4, lines 26-34).

4. Claim 53 is rejected under 35 U.S.C. 102(a) as being anticipated by Whayne et al. (US Patent 6,887,192). Whayne et al. disclose a reinforcing element on the apparatus that includes a plurality of conduits (26, 86, and 88) that form a predetermined shape, and elongated members 52 that, when activated, engage the portion of the endocardial surface.

5. Claim 97 is rejected under 35 U.S.C. 102(b) as being anticipated by Applicant's Admitted Prior Art (AAPA), Buckberg (US Patent 6,024,096). Buckberg discloses, in the claims, a method for reinforcing a portion of the endocardial surface of the heart providing a patch, positioning and releasably attaching the patch to the ventricular wall. See col. 12, lines 41-46, and col. 9, line 67.

6. Claim 116 is rejected under 35 U.S.C. 102(b) as being anticipated by Buckberg (US Patent 6,024,096). Buckberg discloses a method of reinforcing a portion of a

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ventricle of a human heart, where the reinforcing element is attached so the natural contour of the region is maintained (col. 10, lines 59-63).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Whayne et al. (US Patent 6,887,192), in view of Rubin (US Patent 5,910,124). Whayne et al. disclose a ventricular reinforcement apparatus configured to attach to an endocardial surface, and designed with a structure that inhibits overexpansion of the surface during the cardiac cycle. Whayne et al disclose a mechanism for engaging the device with the surface of the ventricle. However, Whayne et al. fails to disclose an adjustment mechanism for the device. Rubin teaches a source of gas pressure applied through the tube to change the dimensions of the reinforcing element. While gas pressure may not be practical for the design of the apparatus of Whayne et al., other mechanisms or modifications to Whayne's device, such as release mechanisms or fluid activation mechanisms exist to actuate the change between a first shape and a second shape. Rubin discloses a pump that provides gas through a tube to the reinforcement device, thereby giving control over the size of the device when expanded, by allowing the user to control the air intake (col. 3, lines 15-50). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide an adjustment mechanism on the device of Whayne et al. in view of the teachings of Rubin.

11. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Whayne et al. (US Patent 6,887,192) in view of Buckberg (US Patent 6,024,096). Whayne et al. disclose a ventricular reinforcement apparatus that acts to stabilize the endocardial surface during contraction and expansion of the ventricle. Whayne et al. fail to disclose a patch in the apparatus. Buckberg teaches a patch 72 that is secured to the endocardial surface and avoids distortion during contraction and expansion, while

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reducing the dead space in the ventricle. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include a reinforcement patch such as that of Buckberg in the device of Whayne et al. to provide an assembly that is durable and reduces the amount of dead space in the heart, while still supporting the surface during contraction and expansion.

12. Claims 24, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whayne et al. (US Patent 6,887,192) in view of Rubin (US Patent 5,910,124). Whayne et al. disclose a ventricular reinforcement apparatus that acts to stabilize the endocardial surface during contraction and expansion of the ventricle. The center of Whayne's device shows an opening at the center that reinforces the conduits that may stem from it. However, Whayne et al. lack a guidewire used to insert the device into the ventricle. Rubin teaches an inserter wire adapted to attach to the ventricular apparatus, inserted into a tube, and used to accurately position the ventricular device within the endocardial surface. Rubin further teaches the ventricular device inserted through a flexible conduit 300, used to position the device in the ventricle on the distal end. A guidewire 52 is used to position the device. Guidewires are commonly used to position elements on the distal end of inserter tubes, due to their maneuverability and low profile shape. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to position the device of Whayne et al. on the endocardial surface using a guidewire as taught by Rubin.

13. Claim 75 is rejected under 35 U.S.C. 103(a) as being unpatentable over Whayne et al. (US Patent 6,887,192), in view of Rubin (US Patent 5,910,124). Whayne et al.

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disclose a system of reinforcing the endocardial surface of a ventricle using a plurality of support links and conduits to attach to the surface, thereby inhibiting overexpansion during the cardiac cycle. The device can be configured multiple shapes to fit the size of the ventricle. However, Whayne et al. lack using a guidewire with a catheter to position the device within the ventricle. Rubin teaches using a guidewire and flexible conduit to insert and position a ventricular device. The use of guidewires to deploy endocardial devices through a catheter or other flexible conduit is well known in the art. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to deploy the device of Whayne et al. using a guidewire as taught in Rubin.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marlee C. Foster whose telephone number is (571) 272-5072. The examiner can normally be reached on Monday to Friday 8:00am to 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

mcf



Marlee C. Foster
Examiner
Art Unit 3731



ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

06/30/06